UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,705	11/18/2003	Asgeir Saebo	NATNUT-08468	5410

72960 7590 03/17/2008
Casimir Jones, S.C.
440 Science Drive
Suite 203
Madison, WI 53711

EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/715,705	SAEBO, ASGEIR	
	Examiner	Art Unit	
	NABILA G. EBRAHIM	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8,10-18,20-24 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-8, 10-18, 20-24 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4-8, 10-18, 20-24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Piomelli or Rodríguez de Fonseca F et al. An anorexic lipid mediator regulated by feeding, Nature. 2001 Nov 8;414 (6860):209-12 (Rodriguez), in view of Dale Boger et al. Exceptionally potent inhibitors of fatty acid amide hydrolase: The enzyme responsible for degradation of endogenous oleamide and anandamide, *PNAS, May 9, 2000, vol. 97 no.10* (Dale), in view of FR 2774263 ('263) and further in view of JP 2001029010 ('010) Piomelli teaches a composition comprising fatty acid ethanol amides, their homologues, and their analogs and to their use as pharmacologically active agents to reduce body fat, reduce food consumption, and modulate lipid metabolism (abstract). the reference teaches that OEA and other fatty acid alkanolamide compounds act to reduce food intake (col. 6, lines 18+). Piomelli suggests a dosages for adult humans, from about 10 to about 1000 mg. Piomelli also

teaches that the fatty acid moiety of the fatty acid alkanolamide compound, homologue, or analog is a fatty acid may be alpha-linolenic acid, and gamma-linolenic acid (col. 3, liens 33+). Piomelli also teaches a dosage form in the form of enteric coated capsule (col. 25, lines 31-49)

Piomelli defines the term "composition", as in pharmaceutical composition, is intended to encompass a product comprising the active ingredient(s), and the inert ingredient(s) that make up the carrier, as well as any product which results, directly or indirectly, from combination, complexation or aggregation of any two or more of the ingredients, or from dissociation of one or more of the ingredients, or from other types of reactions or interactions of one or more of the ingredients. Accordingly, the pharmaceutical compositions of the present invention encompass any composition made by admixing a compound of the present invention and a pharmaceutically acceptable carrier. The term "pharmaceutical composition" indicates a composition suitable for pharmaceutical use in a subject, including an animal or human. A pharmaceutical composition generally comprises an effective amount of an active agent and a pharmaceutically acceptable carrier. Claim 1 and the dependent claims requires a food product and an oleylethanolamide component, the food product according to claim 8 can be a beverage, a prepared food a food ingredient or a dairy product. Accordingly, as known in the art that a carrier of an active compound can be a food or a neutriceutical carrier etc. (evidenced by US publication 20020173511 to Wurtman, Richard et al. paragraph 46). It is deemed that Piomelli's disclosure of a any product comprising the active as a carrier reads on the instant claims.

Rodriguez teaches that oleylethanolamide (OEA) is a natural analogue of the endogenous cannabinoid anandamide. The reference teaches that administration of OEA causes a potent and persistent decrease in food intake and gain in body mass. The

reference indicates that OEA is a lipid mediator involved in the peripheral regulation of feeding. Rodriguez teaches that the dose of OEA is 20 mg/kg or less.

Note that Rodriguez used a composition comprising OEA in the research done on laboratory animals, which are usually used to simulate human responses to different preparations.

Neither of the references teaches a fatty acid amide hydrolase inhibitor in the composition.

Dale teaches that the development of exceptionally potent inhibitors of fatty acid amide hydrolase (FAAH), the enzyme responsible for the degradation of oleamide (an endogenous sleep-inducing lipid), and anandamide (an endogenous ligand for cannabinoid receptors) is detailed in the study. The inhibitors may serve as useful tools to clarify the role of endogenous oleamide and anandamide and may prove to be useful therapeutic agents for the treatment of sleep disorders or pain.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include FAAH in a dietary composition to ensure sleep regulation and to treat pain in a food product in addition to enhancing the effect of reducing food intake as disclosed by Rodriguez.

Rodriguez and Piomelli, and dale recognized the use of oleylethanoamide as a weight regulator, Piomelli added conjugated linoleic acid to enhance the effect of the composition and made into an enteric coated capsule, however, neither of the references teach literally the use of the oleylethanolamide in a nutrient or food product or supplement.

('263) teaches food supplement for reducing levels of monounsaturated fatty acids responsible for fat accumulation in body tissues. The supplement comprises conjugated linoleic acid.

('010) teaches nutrient composition capable of raising an immunological function in an immature state or in a lowered state by enriching the composition with conjugated linoleic acid and stearidonic acid. The nutrient can be milk.

Accordingly, it was obvious to one of ordinary skill in the art at the time the invention was made to use oleylethanolamide disclosed by Piomelli and Rodriguez in a nutrient composition, food supplement or dairy product as disclosed by '263 and '010 to facilitate the use of the compounds and enhance the compliance of the patients in need for weight regulation. The skilled artisan would have expectation of success to have a food supplement, food product or, dairy or a capsule with enteric coating comprising oleylethanolamide and conjugated linoleic acid for patients who need to reduce weight.

Response to Arguments

3. Applicant's arguments with respect to claims 1-2, 4-8, 10-18, 20-24 and 2 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila G Ebrahim/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618